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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,939	09/28/2005	Ian Hughes	PB60179USw	4596
23347	7590	10/15/2010	EXAMINER	
GLAXOSMITHKLINE GLOBAL PATENTS FIVE MOORE DR., PO BOX 13398 MAIL STOP: C.2111F RESEARCH TRIANGLE PARK, NC 27709-3398			HOBBS, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1775	
			NOTIFICATION DATE	DELIVERY MODE
			10/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/550,939	Applicant(s) HUGHES ET AL.	
	Examiner MICHAEL HOBBS	Art Unit 1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,11,14,20-22 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,11,14,20-22 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 07/22/2010 has been considered and entered for the record.
2. Claims 1, 2, 7, 11, 14, 20-22 and 24 are pending further examination upon the merits.

Preliminary Remarks

3. Applicant's amendment overcomes the objection to the specification in the Office Action mailed on 12/24/2009.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 1, 2, 7, 11, 14, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Parce et al. (US 6,046,056).

7. Parce discloses a high-throughput screening assay system for micro-scale fluidic devices. For claim 1, Parce discloses a micro-fluidic system that is a closed loop system (Fig. 6c) that can be operated on a continuous basis (col. 8 lines 10-12) and is fully capable of being automated. Sensors are used within the device to detect signals from the stream such as chromophoric or fluorescent signals (col. 8 lines 26-28, 61-62). The conditions within the channel can be altered with the addition of a test compound (col. 8 lines 35-36) or by the field generated by an electrical fluid direction system (col. 8 lines 62-63). Furthermore, the conditions within the channel can be altered with the addition of a test compound (col. 8 lines 35-36) or by the field generated by an electrical fluid direction system (col. 8 lines 62-63) and Parce further discloses using micro-pipettors or a transfer mechanism for introducing test compounds or reagents to the device (col. 22 lines 25-26). The device is connected to computer (col. 22 lines 4-8) which controls the fluid flow through the chambers and analyzes the data ("receive[s] the sensor signal") from the screening. With regards to "caus[ing] the transfer mechanism to change the reagent combination in the channel structure", this limitation describes what the computer does rather than structurally defines the computer over the prior art and is therefore being interpreted as the intended use of the computer and therefore, the computer of the applied reference is fully capable of performing this action.

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8. With regards to the "automated closed-loop mechanism", Parce discloses the art equivalent structure. This structure consists of a computer, sensor and transfer mechanism as discussed above. Further, the computer is connected to each micro-fluidic chip in the system by way of an adapter where this adapter is connected to the appropriate devices for implementing the operational instructions of the computer and reporting data back to the computer (col. 22 lines 8-13). These devices also include an environmental control that maintains the temperature of each individual device (col. 22 lines 20-24). Therefore, the applied reference of Parce includes the structural elements of the closed-looped mechanism since it both monitors and responds to signals from the micro-fluidic device.

9. It should be noted that applicant used "adapted to" regarding the intended use of the sensor and the computer and that this claim language does not limit the claim to a particular structure. Therefore, this is drawn to the intended use of the apparatus and does not provide a structural limitation that defines over the prior art (see also MPEP 2111.04 and 2114).

10. With regards to claim 2, the sensor sends a signal to the computer as discussed above relating to the fluorescent signal generated from the target molecule (col. 8 lines 26-28). With regards to claim 7, Parce discloses a buffer system (720) that fills the plates on a conveyor system (col. 21 lines 61-64) which the computer is fully capable of operating and the test compounds are within a multi-well plate or array (col. 22 lines 28-30).

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11. With regards to claim 11, Parce discloses the step of programming the computer to operate the system to control the fluid flow and direction of the fluid within the various chips (col. 22 lines 4-6). Further, the computer monitors records and analyzes the data resulting from the screening assays (col. 22 lines 6-8) where the result of the assays are being broadly interpreted as the "predetermined product" of the "predetermined objective". It should be noted that the interfaces for introducing the compound are connected to the robotic system (col. 22 lines 25-27) and the computer is therefore "programmed" to operate the transfer mechanism. Further, the system produces a "product" or result since the system screens a plurality of test compounds for the compounds effect on a biochemical system (col. 2 lines 48-50). This assay would have predetermined objective, such as fluorescence of the target compound (col. 10 lines 42-45) and a predetermined property such as activity of the compound (col. 4 lines 65-67). Finally, since the terms "predetermined property" and "predetermined objective" do not have a specific definition within the specification, any property or objective can reasonably be interpreted to read on these results.

12. With regards to claim 14, Parce discloses a chemical property such as a colorimetric or fluormetric response from the device (col. 10 lines 42-45).

13. For claim 20, Parce discloses using a micro-well plate or array with test compounds (col. 22 lines 28-32) with a computer to control the device where each well has a different test compound (col. 2 lines 48-67) through micro-fluidic channels.

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14. For claim 21, Parce teaches the step where the test compounds are identified or categorized (col. 5 lines 17-21) as effective pharmacological agents for the treatment of disease.

15. Therefore, Parce meets the limitations of claims 1, 2, 7, 11, 14, 20 and 21.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claim 22 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (US 6,046,056).

20. Parce discloses using the system as discussed above for claim 1 (col. 2 lines 48-65) for the high-throughput micro-fluidic system. With regards to claim 22, Parce does not specifically teach the step where the computer operates the system "heuristically" (learns) or that the "predetermined property" is optimized. However, the use of a computer or algorithm that adjusts the parameters based on feed back from the system is within the skills of one of ordinary skill in the art. Further, Parce implies that the computer optimizes the system for the reaction within the micro-channels where the monitored property is optimized for the target solution being screened by the devices. Therefore, it would be obvious to one of ordinary skill in the art to employ an "intelligent" computer and optimize the reaction based on the teachings of Parce in order to determine which of the samples are contain the most effective pharmacological agents.

21. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (US 6,046,056) in view of Wolk et al. (US 2002/0009392 A1).

22. With regards to claim 24, Parce discloses a controller that receives a signal from sensors and then modifies the flow through the channel or adjusts the temperature based on instructions (or a predetermined objective) programmed into the computer. Moreover, this computer, as discussed above, is connected to adapter devices that

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connect to various sensors and devices necessary to carry out the reaction. Further, the device is programmed to control the fluid flow and direction of flow within the channels based on the operational instructions within the computer and data received from the devices. Parce further discloses that data (or a signal) relating to the temperature of the device can be received from the computer and is adjusted by the computer in order to maintain the optimal temperature for performing the assay (or objective) (see col. 22 lines 4-24). However, Parce differs from the instant claim where the computer is programmed to initiate the steps of comparing the signal from the sensor to the predetermined objective and then uses the transfer mechanism to achieve the desired result.

23. Wolk discloses a micro-fluidic device that reduces the fluid carryover from sample wells that includes for claim 24 a computer that is connected to a detection system ([0087]) where this detection system can monitor properties of the reaction within more than one channel ([0075]). Further, the sensor sends a signal to the computer where the computer has software that converts the signal into assay result information (i.e. kinetic data of modulator activity; [0075]) where this result is being interpreted as a biological property. The computer receives data from the one or more sensors within the system, interprets the data and uses the data to initiate further controller instructions in accordance with the programming or predetermined objective such as monitoring and controlling the flow rates and temperature. Further, the computer software controls the injection or withdrawal of material from the channels ([0088]).

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24. Therefore, it would be obvious for one of ordinary skill in the art to employ the computer and software as suggested by Wolk with the computer and micro-fluidic system of Parce in order to obtain the predictable result of controlling the assay within the micro-channels.

Response to Arguments

25. Applicant's arguments filed 07/22/2010 have been fully considered but they are not persuasive.

26. In the first three paragraphs on page 5, applicant summarizes the amendments made to the claims.

27. In the fourth paragraph on page 5, applicant addresses the objection to the claims for lacking antecedent basis in the specification. Applicant's amendment, as mentioned above, overcomes this objection.

28. Applicant's traversal of the rejection of record begins in the fifth paragraph on page 5 and continues through the bottom of page 8.

29. Starting in the fifth paragraph on page 5, applicant summarizes the 35 USC 102(b) rejections and in the last paragraph on page 5 and continuing to page 6, applicant presents the claimed invention as defined by claim 1.

30. In the first full paragraph on page 6, applicant points out how the transfer mechanism operates with the computer. This has been noted, but this passage is

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drawn to the operation of the apparatus and does not present a structural difference between the art of record and the claimed invention.

31. In the last paragraph on page 6, applicant argues that Parce is silent on what basis the test compounds are added and makes no mention of how the data is used. However, Parce discloses that the signal is a product of catalytic action on a chromogenic or fluorogenic substrate that is representative of the interaction between a labeled ligand with a receptor (see col. 8 lines 36-34). Also, the "use" of this signal, as claimed, does not provide a structural limitation that defines the claimed invention over the prior art. In the first paragraph on page 7, applicant re-iterates that the applied reference does not disclose an automated closed-loop control mechanism that determines what compound should be sent through the channel. Again, the closed-looped control mechanism or feedback control loop of the instant application includes a sensor, a transfer mechanism and a computer that receives the signal and then activates the transfer mechanism. As stated previously and restated in this action, the applied reference of Parce includes a sensor for monitoring the system such as temperature, conductivity and potentiometric sensors (see col. 10 lines 60-63). As these sensors are connected to the computer via an adapter device, and can, for example, adjust the temperature within the device (col. 22 lines 20-25). With regards to the autonomous control of the device, while the fluid flow is continuous, the assays are carried out in a micro-laboratory system that allows for the integration and automation of the elements needed to carry out the assays (col. 7 lines 59-61). Moreover, the micro-laboratory systems of Parce are automated (see col. 7 lines 58-62).

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32. Regarding applicant's argument that there is no reference to a computer connected to a sensor, please refer to column 22 lines 7-20 where the sensors are connected to the computer via an adapter.

33. Applicant argues that the applied reference does not disclose the inter-relationship between the sensor, computer and transfer mechanism. Applicant mischaracterizes the reference as the applied reference discloses that all the devices are connected to the computer (see col. 22 lines 4-8) where the sensors and micro-pipettor are the devices connected to the computer. Furthermore, as applicant has defined the "closed-loop" system as the sensor, transfer mechanism and computer, the applied reference of Parce anticipates this control system since there is not a definition within the specification that bars the application of the art of record to the claims.

34. In the fourth paragraph on page 7, applicant appears to be arguing that more than one embodiment within the reference has been applied to the instant claims. This appears to be a mischaracterization of the reference since the micro-laboratory system can be operated in either in a continuous flow assay system or as a serial in parallel assay system and the sections cited where to the continuous flow assay system configuration of the micro-laboratory system and not between two different embodiments.

35. Starting on the bottom of page 7 and continuing to page 8, applicant is reiterating the above arguments that the art of record does not perform the intended use of the claimed invention. These arguments are drawn to the intended use of the claimed invention and does not provide a structural limitation that defines over the prior

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art (see MPEP 2114). Further, the limitation of "streamlin[ing]" the process is a limitation relied upon, but not claimed by the applicant.

36. Finally, the last four paragraphs on page 8 re-iterate the above arguments which have already been addressed.

Conclusion

37. No claims are allowed.

38. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1775

/M. H./
Examiner, Art Unit 1797